

EXHIBIT A

UNITED STATES DISTRICT COURT
DISTRICT OF DELAWARE

AZURITY PHARMACEUTICALS, INC.,

Plaintiff,

v.

BIONPHARMA INC.,

Defendant.

C.A. No. 21-1286-LPS
C.A. No. 21-1455-LPS

**DEFENDANT BIONPHARMA'S FIRST SET OF
REQUESTS FOR PRODUCTION OF DOCUMENTS AND THINGS**

Pursuant to Rules 26 and 34 of the Federal Rules of Civil Procedure, Defendant Bionpharma Inc. (“Bionpharma”), submits its First Set of Requests for Production of Documents and Things directed to Plaintiff Azurity Pharmaceuticals, Inc. (“Plaintiff” or “Azurity”), and request that Plaintiff produce the documents and things requested herein within thirty (30) days of service to the offices of Taft, Stettinius & Hollister LP, 111 E. Wacker Drive, Suite 2800, Chicago, IL 60601, or at such other time and place as may be mutually agreed upon by the parties, in accordance with the instructions and definitions below.

DEFINITIONS AND INSTRUCTIONS

Bionpharma hereby incorporates by reference, as though fully set forth herein, the Definitions and Instructions in Bionpharma’s First Set of Requests for the Production of Documents and Things (Nos. 1-91), and in Bionpharma’s First Set of Interrogatories (No. 1), both served November 20, 2019 in connection with the *Silvergate Pharmaceuticals, Inc. v. Bionpharma Inc.*, C.A. Nos. 18-1962 and 19-1067 (D. Del.) cases.

I. SUPPLEMENTAL DEFINITIONS

1. The term “Alkem” means to Alkem Laboratories Ltd., as well as any related entities, partners, corporate parent, subsidiaries, affiliates, predecessors in interest, successors-in-interest, as well as any of their present or former officers, directors, employees, agents, representatives, attorneys and each person acting or purporting to act on their behalf. Alkem also means the defendant in *Silvagate Pharmaceuticals, Inc. v. Alkem Laboratories Ltd.*, Case No. 19-cv-2100 (D. Del.), and any other Related Patent Litigation.

2. The term “Amneal” means Amneal Pharmaceuticals LLC, as well as any related entities, partners, corporate parent, subsidiaries, affiliates, predecessors in interest, successors-in-interest, as well as any of their present or former officers, directors, employees, agents, representatives, attorneys and each person acting or purporting to act on their behalf. Amneal also means the defendant Amneal in *Silvagate Pharmaceuticals, Inc. v. Amneal Pharmaceuticals LLC.*, CA No. 19-cv-678 (D. Del.); *Silvagate Pharmaceuticals, Inc. v. Amneal Pharmaceuticals LLC*, CA No. 20-cv-01255 (D. Del.), and any other Related Patent Litigation.

3. The term “Annora” means to Annora Pharma Private Limited, as well as any related entities, partners, corporate parent, subsidiaries, affiliates, predecessors in interest, successors-in-interest, as well as any of their present or former officers, directors, employees, agents, representatives, attorneys and each person acting or purporting to act on their behalf. Annora also means the defendant in *Silvagate Pharmaceuticals, Inc. v. Annora Pharma Private Limited*, Case No. 20-cv-753 (D. Del.) and *Silvagate Pharmaceuticals, Inc. v. Annora Pharma Private Limited*, Case No. 21-cv-196 (D. Del.), and any other Related Patent Litigation.

4. The term “Aurobindo” means Aurobindo Pharma Ltd. and/or Aurobindo Pharma USA, Inc., as well as any related entities, partners, corporate parent, subsidiaries, affiliates, predecessors in interest, successors-in-interest as well as any of their present or former officers,

directors, employees, agents, representatives, attorneys and each person acting or purporting to act on their behalf. The term “Aurobindo” also means the defendants in *Azurity Pharmaceuticals, Inc. v. Aurobindo Pharma Ltd.*, CA No. 21-cv-1707 (D. Del.), and any other Related Patent Litigation.

5. The term “Azurity” means Plaintiff Azurity Pharmaceuticals, Inc., and (i) all respective predecessors-in interest and successors-in-interest, including but not limited to CutisPharma, Inc. and Silvergate Pharmaceuticals, Inc.; (ii) all respective past or present corporate parents, subsidiaries, affiliates, divisions, officers, directors, employees, agents, consultants, investigators, attorneys, and representatives; (iii) any other person acting on their behalf or on whose behalf they have acted or are acting; or (iv) any other person or entity otherwise subject to their control or which controls or controlled them. Where applicable, this definition shall include all persons having a former or current ownership interest in any of the Enalapril Liquid Patents or Related Patent Application(s).

6. The term “Azuritiy-CoreRx LSA” shall mean the Litigation Settlement Agreement between Azurity and CoreRx.

7. The term “CoreRx” means to CoreRx, Inc., as well as any related entities, partners, corporate parent, subsidiaries, affiliates, predecessors in interest, successors-in-interest, including but not limited to NovaQuest Capital Management, etc. as well as any of CoreRx’s present or former officers, directors, employees, agents, representatives, attorneys and each person acting or purporting to act on their behalf. CoreRx also means defendant CoreRx in *Azurity Pharm., Inc. v. CoreRx, Inc.*, C.A. No. 21-1522-LPS (D. Del.); *Azurity Pharm., Inc. v. CoreRx, Inc.*, C.A. No. 8:21-cv-2515 (M.D. Fla.) and any other case related to Epaned.

8. The Term “Enalapril Liquid Patents” means, collectively, the First, Second, and Third Wave Patents.

9. The term “First Wave Patents” means ’008, ’442, ’745, and ’987 patents.

10. The term “First Wave Suits” means *Silvergate Pharmaceuticals, Inc. v. Bionpharma Inc.*, C.A. Nos. 18-1962 and 19-1067 (D. Del.).

11. The term “MMSA” shall mean the November 2020 Master Manufacturing Supply Agreement between Bionpharma and CoreRx.

12. The term “NovaQuest” means to NovaQuest Capital Management LLC, Inc., as well as any related entities, partners, corporate parent, subsidiaries, affiliates, predecessors in interest, successors-in-interest as well as any of their present or former officers, directors, employees, agents, representatives, attorneys and each person acting or purporting to act on their behalf.

13. The term “Plaintiff” means Azurity, as well as any related entities, partners, corporate parent, subsidiaries, affiliates, predecessors in interest, successors-in-interest, including but not limited to CutisPharma, Inc. and Silvergate Pharmaceuticals, Inc., etc. as well as any of their present or former officers, directors, employees, agents, representatives, attorneys and each person acting or purporting to act on their behalf. Where applicable, this definition shall include all persons having a former or current ownership interest in any of the Enalapril Liquid Patents or Related Patent Application(s).

14. The term “Related Patent Applications” means any and all patent applications or patents (U.S. and foreign) corresponding to, or claiming priority from, the Enalapril Liquid Patents whether or not abandoned and whether or not issued, or to which the Enalapril Liquid Patents,

whether or not abandoned and whether or not issued, claim priority or any and all applications or patents (U.S. and foreign) directed to enalapril liquids.

15. The term “Related Patent Litigation” means any lawsuit filed by or against Plaintiff or any other entity or person concerning or relating to any enalapril solution, Epaned and/or the Enalapril Liquid Patents or Related Patent Applications.

16. The term “Second Wave Patents” means U.S. Patent Nos. 10,786,482 B2 (“482 patent”); 10,918,621 B2 (“621 patent”); 10,772,868 B2 9 (“868 patent”)

17. The term “Second Wave Suit” means *Silvergate Pharmaceuticals, Inc. v. Bionpharma Inc.*, C.A. No. 20-1256 (D. Del.).

18. The term “Third Wave Patents” means U.S. Patent Nos. 11,040,023 B2 (“023 patent”) and 11,141,405 (“405 patent”).

19. The term “Third Wave Suits” means instant actions, *Azurity Pharmaceuticals, Inc. v. Bionpharma Inc.*, C.A. Nos. 21-1286-LPS, 21-1455-LPS (D. Del.).

REQUESTS FOR PRODUCTION

1. All documents and things concerning U.S. Patent Application No. 16/991,575 ('621 patent) including any applications, prosecution history, prior art, documents and things authored by any inventors of this patent application, and communications with the PTO or FDA regarding this patent application.

2. All documents and things concerning U.S. Patent Application No. 17/150,587 ('023 patent) including any applications, prosecution history, prior art, documents and things authored by any inventors of this patent application, and communications with the PTO or FDA regarding this patent application.

3. All documents and things concerning U.S. Patent Application No. 17/228,024 ('405 patent) including any applications, prosecution history, prior art, documents and things authored by any inventors of this patent application, and communications with the PTO or FDA regarding this patent application.

4. All documents and things concerning any discussion, consideration or decision by Plaintiff regarding whether to file, re-file, or prosecute any patent application relating to the Enalapril Liquid Patents and/or Related Patent Applications.

5. All references cited or referred to during the prosecution of the Second Wave Patents, Third Wave Patents, or Related Patent Applications, including all references cited on the face of the Second Wave Patents and Third Wave Patents.

6. All documents and things concerning any prior use, patent, publication, or other prior art that was cited, referred to, or relied upon, during the prosecution of the Second Wave Patents, Third Wave Patents, or Related Patent Applications.

7. All documents and things concerning any communications, patent office filings, or judicial or regulatory filings concerning Second Wave Patents, Third Wave Patents, or Related Patent Applications.

8. All documents, communications and things relating to the Examples set forth in the Enalapril Liquid Patents, Related Patent Applications, and any declarations, including but not limited to declarations from inventor(s) of the Enalapril Liquid Patents and Related Patent Applications, submitted to the USPTO, including but not limited to, all data relating to any testing and any laboratory notebooks related to the Examples.

9. All documents and things concerning any novelty, patentability, validity, infringement, state-of-the-art, unenforceability or right-to-use search, investigation, report,

opinion, study, or analysis, whether formal or informal, that relates to the Second Wave Patents or to the Third Wave Patents.

10. All documents supporting or undermining any assertions of secondary considerations of non-obviousness that Plaintiff intends to raise, intended to raise, or have raised in the Third Wave Suits, including but not limited to, proof of nexus, profit margins and marketing expenditures.

11. Documents sufficient to show the ownership interest of NovaQuest in Azurity and CoreRx.

12. Documents sufficient to show organizational structure of, and corporate relationship between, Azurity, NovaQuest, and CoreRx.

13. Documents sufficient to show the ownership of Azurity, NovaQuest, and CoreRx.

14. All documents and things concerning relationships, agreements, and communications between Azurity and either NovaQuest or CoreRx or both (or any affiliate or subsidiary thereof) as they relate to the Enalapril Liquid Patents, Related Patent Applications, Epaned, and/ or NDA No. 208686.

15. Any settlement agreements between Azurity and either NovaQuest or CoreRx or both (or any affiliate or subsidiary thereof) as they relate to Enalapril Liquid Patents, Related Patent Applications, Epaned, and/or NDA No. 208686.

16. All documents and things referring or relating to or constituting any assignment, license, contract, authorization, agreement, stipulation, settlement, or negotiations involving Plaintiff in regard to any legal right to any of the Enalapril Liquid Patents or Related Patent Applications, or to any legal right to any of the alleged inventions or products referred to in

Plaintiff's Complaint in the Third Wave Suits, including, but not limited to, enalapril solution and/or Epaned.

17. All documents and things referring or relating to or constituting any assignment, license, contract, authorization, agreement, stipulation, settlement, or negotiations involving Plaintiff and Amneal, Aurobindo, Annora, and/or Alkem in regard to any legal right to any of the Enalapril Liquid Patents or Related Patent Applications, or to enalapril solution and/or Epaned.

18. All documents and things concerning any relationship that exists or has existed between Azurity and any other defendant in the Related Epaned Litigations pertaining to enalapril and/or any of the Enalapril Liquid Patents, including, but not limited to, any co-marketing agreements or authorized generic agreements.

19. All documents and things referring or relating to any valuations of the indemnification granted by Azurity to CoreRx in the settlement agreement between Azurity and CoreRx regarding Third Wave Patents.

20. All documents and things concerning the Azurity-CoreRx LSA, including any drafts of the Azurity-CoreRx LSA.

21. All documents and communications relating to actual or potential generic competition to Epaned.

22. All documents and communications with NovaQuest relating to Bionpharma, Bionpharma's ANDA Product, or any actual or potential competition to Epaned.

23. All documents and communications with NovaQuest relating to CoreRx's relationship with Bionpharma, including documents and communications pertaining to the MMSA.

24. All documents and communications with CoreRx relating to generic competition to Epaned, the Enalapril Liquid Patents, Bionpharma's ANDA Product, the MMSA, the Azurity-CoreRx LSA, NovaQuest, and any other enalapril ANDA filer.

25. All documents and communications relating to generic competition to Epaned, the Enalapril Liquid Patents, Bionpharma's ANDA Product, CoreRx, the Azurity-CoreRx LSA, NovaQuest, and any other ANDA filer, to or from any board member, past or present, of CoreRx, including Messrs. Nailesh Bhatt, Vern Davenport, Jeff Edwards, and Frank Leo.

26. All documents and communications relating to generic competition to Epaned, the Enalapril Liquid Patents, Bionpharma's ANDA Product, CoreRx, the Azurity-CoreRx LSA, NovaQuest, and any other ANDA filer, to or from any board member, past or present, of Azurity, including Messrs. Nailesh Bhatt, Richard Blackburn, Vern Davenport, Jeff Edwards, Frank Leo, Amit Patel, and Dave Ritchie.

27. All documents and things, including communications between Azurity and NovaQuest, relating to NovaQuest's decision, negotiation, or agreement to take an ownership interest in CoreRx.

28. All documents, communications, and things relating to Azurity's decision to sue CoreRx for alleged infringement of Third Wave Patents.

29. All documents, communications, and things between Azurity and NovaQuest relating to Azurity's decision to sue CoreRx for alleged infringement of Third Wave Patents.

30. All documents and things pertaining to Azurity's decision to voluntarily dismiss *Azurity Pharmaceuticals, Inc. v. CoreRx, Inc.*, C.A. No. 21-1522-LPS (D. Del.) and *Azurity Pharmaceuticals, Inc. v. CoreRx, Inc.*, C.A. No. 21-2515-VMC-SPF (M.D. Fla.).

31. All documents and things related to Plaintiff's sales and marketing expenditure for Epaned.

32. All sales data relating to Epaned generated or dating from the first day of commercial sale of the product to the present.

33. All profit and sales projections for Epaned.

34. All profit and sales projections for Epaned taking into account any contemplated or actual generic competition to Epaned.

35. All documents and things concerning the projected and/or actual damages to Azurity caused by launch of Bionpharma's ANDA Product.

36. All documents and things concerning the projected and/or actual damages to Azurity caused by launch of Annora's ANDA Product.

37. All documents and things concerning the projected and/or actual damages to Azurity caused by the launch of any enalapril liquid generic to Epaned.

38. All documents since the first commercial launch of Epaned sufficient to describe the gross and net sales, market share, gross and net profits; sales and profit forecasts; advertising, promotion, presentation, description, and/or explanation of Epaned, including, but not limited to, materials concerning market research regarding Epaned, customer/physician surveys, sales representative materials, and all market analyses.

39. All documents and things sufficient to show actual gross and net profits from Epaned sales.

40. All documents and communications (including from consultants, market analysts, attorneys, or other third parties), including any opinions of counsel, concerning the strength(s) or

weakness(es) of any of the Enalapril Liquid Patents and/or the merits or expected outcome of any of the First Wave Suits, Second Wave Suit, Third Wave Suits and/or Related Patent Litigations.

41. All documents and things concerning any opinions of counsel concerning any of the Enalapril Liquid Patents, the First Wave Suits, the Second Wave Suit, the Third Wave Suits, and/or Related Patent Litigations.

42. All documents and things concerning the value of, damages for infringement, and/or royalties for licenses in connection with Enalapril Liquid Patents and Related Patent Applications.

43. All documents and things concerning the value of, damages for infringement, and/or royalties for licenses in connection with the Third Wave Patents.

44. Documents sufficient to identify each drug that competes with Epaned.

45. Documents sufficient to identify each hypertension treatment that competes with Epaned.

46. Documents sufficient to identify each symptomatic heart failure treatment that competes with Epaned.

47. Documents sufficient to identify each asymptomatic left ventricular dysfunction treatment that competes with Epaned.

48. Documents sufficient to describe the cost, availability, and distribution of any product or treatment that competes with Epaned or is used to treat hypertension, symptomatic heart failure, and/or symptomatic heart failure.

49. All documents and things relating to the gross and net sales, market share, gross and net profits; sales and profit forecasts; advertising, promotion, presentation, description, and/or

explanation of any product or treatment that competes with Epaned or is used to treat hypertension, symptomatic heart failure, and/or symptomatic heart failure.

50. Documents sufficient to show the pricing, whether proposed, offered or actual, of all marketed dosages and forms of Epaned.

51. All documents and things relating to any price changes considered or implemented for Epaned in response to any perceived or actual competition.

52. All strategic planning documents for Epaned, including each marketing plan, 5-year plan, or market analysis for Epaned, and any documents or communications concerning such strategic planning documents.

53. All documents relating to any market in which Epaned competes, including all documents relating to the market share of Epaned and/or any product or therapy that actually or potentially competes with Epaned, any competitive analysis of any product or therapy that actually or potentially competes with Epaned, and the impact (including impact on sales (in dollars or unit volume) and/or profits) on Azurity of any product or therapy that actually or potentially competes with Epaned.

54. All documents concerning the advertising, promotion or marketing of Epaned, including but not limited to, advertisements, drafts of advertisements, market research, advertising budgets, results of focus groups or consumer surveys, letters to healthcare providers and direct-to-consumer advertising.

55. One copy of each detail aid, visual aid, product monograph and/or piece of promotional or professional literature used by Plaintiff's representatives to detail or promote Epaned to physicians and/or other health care professionals.

56. All detail and/or sample audits, including but not limited to IMS data, relating to Epaned.

57. Any market research, physician surveys, or prescriptions data analysis for Epaned or for any treatment that competes with Epaned or that is used to treat hypertension, symptomatic heart failure, and/or symptomatic heart failure.

58. All studies, analyses, compilations or reports of physicians' impressions or opinions concerning Epaned.

59. All analyses, memoranda, charts, studies or other data recording or reporting the market share of Epaned, whether actual or projected.

60. All documents and things concerning any planned or implemented response to generic competition for Epaned.

61. All documents and communications relating to strategies or attempts to prevent or delay generic competition to Epaned.

62. All documents and communications relating to generic competition to Epaned, including evaluation of ANDA filers.

63. All documents concerning competition for the sale of any enalapril product.

64. All documents, communications, and things relating to Azurity's decision to sue, and/or to maintain any suit against, Bionpharma for alleged infringement of First Wave Patents, including:

- a. All documents, communications, and things relating to the merits of Azurity's claims, including whether any objective basis exists for them.
- b. All documents, communications, and things relating to the likelihood that Azurity would obtain any relief on its claims;

- c. All documents, communications, and things relating to Azurity's legal and business objectives from asserting the claims, including the effect of this and/or other patent litigations on Bionpharma's financial ability and/or willingness to defend against the claims; and
- d. All documents, communications and things relating to the effect of Azurity's suing, or maintaining any suit, against Bionpharma for alleged infringement of First Wave Patents, including any effect on Azurity's sales (in dollars or unit volume) or profit margins for Epaned.

65. All documents, communications, and things relating to Azurity's decision to sue, and/or to maintain any suit against, Bionpharma for alleged infringement of Second Wave Patents, including:

- a. All documents, communications, and things relating to the merits of Azurity's claims, including whether any objective basis exists for them.
- b. All documents, communications, and things relating to the likelihood that Azurity would obtain any relief on its claims;
- c. All documents, communications, and things relating to Azurity's legal and business objectives from asserting the claims, including the effect of this and/or other patent litigations on Bionpharma's financial ability and/or willingness to defend against the claims; and
- d. All documents, communications and things relating to the effect of Azurity's suing, or maintaining any suit, against Bionpharma for alleged infringement of Second Wave Patents, including any effect on Azurity's sales (in dollars or unit volume) or profit margins for Epaned.

66. All documents, communications, and things relating to Azurity's decision to sue, and to maintain its suit against, Bionpharma for alleged infringement of Third Wave Patents, including:

- a. All documents, communications, and things relating to the merits of Azurity's claims, including whether any objective basis exists for them.
- b. All documents, communications, and things relating to the likelihood that Azurity would obtain any relief on its claims;
- c. All documents, communications, and things relating to Azurity's legal and business objectives from asserting the claims, including the effect of this and/or other patent litigations on Bionpharma's financial ability and/or willingness to defend against the claims; and
- d. All documents, communications and things relating to the effect of Azurity's suing, or maintaining any suit, against Bionpharma for alleged infringement of Third Wave Patents, including any effect on Azurity's sales (in dollars or unit volume) or profit margins for Epaned.

67. All documents and things referenced in Azurity's Rule 26(a)(1) disclosures.

68. All documents and things Azurity intends to rely on to prove its claims in the Third Wave Suits.

Dated: March 21, 2022

/s/ Megan C. Haney

John C. Phillips, Jr. (#110)

Megan C. Haney (#5016)

PHILLIPS, McLAUGHLIN & HALL, P.A.

1200 North Broom Street

Wilmington, DE 19806
(302) 655-4200
jcp@pmhdelaw.com
mch@pmhdelaw.com

Of Counsel:

Andrew M. Alul
Roshan P. Shrestha, Ph.D.
TAFT STETTINIUS & HOLLISTER LLP
111 East Wacker Drive, Suite 2800
Chicago, IL 60601
312-527-4000
aalul@taftlaw.com
rshrestha@taftlaw.com

Aaron M. Johnson
TAFT STETTINIUS & HOLLISTER LLP
2200 IDS Center
80 South Eighth Street
Minneapolis, MN 55402
612-977-8400
ajohnson@taftlaw.com

Christopher J. Kelly
MAYER BROWN LLP
Two Palo Alto Square
3000 El Camino Real
Palo Alto, CA 94306-2112
(650) 331-2000
cjkelly@mayerbrown.com

*Attorneys for Defendant
Bionpharma Inc.*

CERTIFICATE OF SERVICE

I, Megan C. Haney, hereby certify that on March 21, 2022, a copy of Defendant Bionpharma First Set of Requests for Production of Documents and Things was served upon the following counsel of record in the manner indicated below:

VIA EMAIL

Jack B. Blumenfeld
Megan E. Dellinger
Morris, Nichols, Arsh & Tunnell LLP
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
jblumenfeld@morrisnichols.com
mdellinger@morrisnichols.com

Wendy L. Devine
Kristina M. Hanson
Nicholas Halkowski
Wilson Sonsini Goodrich & Rosati
One Market Plaza, Spear Tower, Suite 3300
San Francisco, CA 94105
wdevine@wsgr.com
thanson@wsgr.com
nhalkowski@wsgr.com

Natalie J. Morgan
Evan Sumner
Wilson Sonsini Goodrich & Rosati
12235 El Camino Real, Suite 200
San Diego, CA 94105
nmorgan@wsgr.com
esumner@wsgr.com

Granville C. Kaufman
Ty W. Callahan
Wilson Sonsini Goodrich & Rosati
633 West Fifth Street, Suite 1550
Los Angeles, CA 90071
gkaufman@wsgr.com
tcallaham@wsgr.com

Jeffrey C. Bank
Wilson Sonsini Goodrich & Rosati
1700 K Street, NW, Fifth Floor

Washington, DC 20006
jbank@wsgr.com

/s/ Megan C. Haney
Megan C. Haney (No. 5016)

EXHIBIT B

UNITED STATES DISTRICT COURT
DISTRICT OF DELAWARE

AZURITY PHARMACEUTICALS, INC.,

Plaintiff,

v.

BIONPHARMA INC.,

Defendant.

C.A. No. 21-1286-LPS
C.A. No. 21-1455-LPS

DEFENDANT BIONPHARMA'S FIRST SET OF INTERROGATORIES

Pursuant to Rules 26 and 33 of the Federal Rules of Civil Procedure, Defendant Bionpharma Inc. (“Bionpharma”), propounds its First Set of Interrogatories directed to Plaintiff Azurity Pharmaceuticals, Inc. (“Plaintiff” or “Azurity”) which is to be answered by Plaintiff within the time period required by law, or as otherwise agreed to by counsel or ordered by the Court.

DEFINITIONS AND INSTRUCTIONS

Bionpharma hereby incorporates by reference, as though fully set forth herein, the Definitions and Instructions set forth in Bionpharma’s First Set of Requests for the Production of Documents and Things (Nos. 1-91), and in Bionpharma’s First Set of Interrogatories (No. 1), both served November 20, 2019 in connection with the *Silvergate Pharmaceuticals, Inc. v. Bionpharma Inc.*, C.A. Nos. 18-1962 and 19-1067 (D. Del.) cases, and the Definitions and Instructions set forth in Bionpharma’s First Set of Requests for Production of Documents and Things, served concurrently herewith in connection with the instant suits.

INTERROGATORIES

INTERROGATORY NO. 1. For each asserted claim of the Third Wave Patents that Plaintiff contends is valid (or not invalid), describe in detail each legal basis and all facts on which Plaintiff may rely to support their contention that such asserted claim is valid (or not

invalid), including any secondary considerations of nonobviousness, and identify the three persons associated with Plaintiff with the most knowledge concerning the facts providing the basis for Plaintiff's contention, and the documents and things on which Plaintiff may rely to support Plaintiff's contention.

INTERROGATORY NO. 2. For each asserted claim of the Third Wave Patents, identify whether Plaintiff intends to raise any assertion of secondary considerations of nonobviousness in connection with any allegation that such claim is invalid for obviousness, and, if so, identify the specific secondary considerations on which Plaintiff intends to rely (i.e., commercial success, long-felt need, failure of others, etc.), all documents supporting Plaintiff's secondary considerations assertions (including but not limited to, in the case of commercial success, proof of nexus, profit margins, marketing expenditures, and the like), and the three persons associated with Plaintiff with the most knowledge regarding such secondary considerations and documents.

INTERROGATORY NO. 3. To the extent that Azurity contends Bionpharma does not have a license to the Third Wave Patents under the MMSA, explain in detail the factual and legal bases and supporting evidence for Azurity's contention, including whether and why Azurity believes it is not a party to the MMSA, and including whether and why Azurity believes it does not fall within the definition of "CoreRx" in the MMSA as an "Affiliate," as that term is defined in Section 1.1 of the MMSA.

INTERROGATORY NO. 4. Describe in detail the relationship between Azurity, NovaQuest, and CoreRx, including any ownership interest that NovaQuest has in Azurity and/or CoreRx, and the extent of such ownership interest.

Dated: March 21, 2022

/s/ Megan C. Haney

John C. Phillips, Jr. (#110)
Megan C. Haney (#5016)
PHILLIPS, McLAUGHLIN & HALL, P.A.
1200 North Broom Street
Wilmington, DE 19806
(302) 655-4200
jcp@pmhdelaw.com
mch@pmhdelaw.com

Of Counsel:

Andrew M. Alul
Roshan P. Shrestha, Ph.D.
TAFT STETTINIUS & HOLLISTER LLP
111 East Wacker Drive, Suite 2800
Chicago, IL 60601
312-527-4000
aalul@taftlaw.com
rshrestha@taftlaw.com

Aaron M. Johnson
TAFT STETTINIUS & HOLLISTER LLP
2200 IDS Center
80 South Eighth Street
Minneapolis, MN 55402
612-977-8400
ajohnson@taftlaw.com

Christopher J. Kelly
MAYER BROWN LLP
Two Palo Alto Square
3000 El Camino Real
Palo Alto, CA 94306-2112
(650) 331-2000
cjkelly@mayerbrown.com

*Attorneys for Defendant
Bionpharma Inc.*

CERTIFICATE OF SERVICE

I, Megan C. Haney, hereby certify that on March 21, 2022, a copy of Defendant Bionpharma Inc.'s First Set of Interrogatories was served upon the following counsel of record in the manner indicated below:

VIA EMAIL

Jack B. Blumenfeld
Megan E. Dellinger
Morris, Nichols, Arsh & Tunnell LLP
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
jblumenfeld@morrisnichols.com
mdellinger@morrisnichols.com

Wendy L. Devine
Kristina M. Hanson
Nicholas Halkowski
Wilson Sonsini Goodrich & Rosati
One Market Plaza, Spear Tower, Suite 3300
San Francisco, CA 94105
wdevine@wsgr.com
thanson@wsgr.com
nhalkowski@wsgr.com

Natalie J. Morgan
Evan Sumner
Wilson Sonsini Goodrich & Rosati
12235 El Camino Real, Suite 200
San Diego, CA 94105
nmorgan@wsgr.com
esumner@wsgr.com

Granville C. Kaufman
Ty W. Callahan
Wilson Sonsini Goodrich & Rosati
633 West Fifth Street, Suite 1550
Los Angeles, CA 90071
gkaufman@wsgr.com
tcallaham@wsgr.com

Jeffrey C. Bank
Wilson Sonsini Goodrich & Rosati
1700 K Street, NW, Fifth Floor

Washington, DC 20006
jbank@wsgr.com

/s/ Megan C. Haney
Megan C. Haney (No. 5016)

EXHIBIT C

Poonai, Alexander

From: Shrestha, Roshan P. <rshrestha@taftlaw.com>
Sent: Tuesday, March 8, 2022 10:54 AM
To: Hanson, Tina
Cc: Bank, Jeffrey; Alul, Andrew M.; Kelly, Christopher J.; Poonai, Alexander; Johnson, Aaron; Jack Phillips; Megan C. Haney; Dellinger, Megan E.; Raucci, Anthony D.
Subject: Re: Azurity Pharmaceuticals v. Bionpharma, Inc. [MB-AME.FID2745800]
Attachments: image025.png; image026.png; image027.png; image028.png; image029.png; image030.png; image001.png; image002.png; image003.png; image004.png; image005.png; image006.png; image007.png; image008.png; image009.png; image010.png; image011.png; image012.png; Azurity_Bionpharma_ Stipulation re Motion to Dismiss Briefing.docx

[External]

Tina, the stipulation is fine with Bionpharma.

As you should well know, Bionpharma is not interested in “discuss[ing] a faster trial schedule.” In fact, depending on the level of cooperation we get from Azurity in discovery—particularly with respect to discovery related to Bionpharma’s antitrust claims—Bionpharma may be seeking an extension of the current schedule.

- Roshan

On Mar 3, 2022, at 10:52 AM, Hanson, Tina <thanson@wsgr.com> wrote:

[EXTERNAL MESSAGE]

Roshan,

Attached is a draft stipulation regarding the Parties’ agreed-upon schedule for the briefing.

If Bionpharma would like to discuss a faster trial schedule, we would be happy to do so. But as the current deadline for fact discovery is December 12 of this year, the briefing schedule should not jam anything up.

Best,
Tina

From: Shrestha, Roshan P. <rshrestha@taftlaw.com>
Sent: Wednesday, March 2, 2022 11:05 AM
To: Hanson, Tina <thanson@wsgr.com>; Bank, Jeffrey <jbank@wsgr.com>; Alul, Andrew M. <AAAlul@taftlaw.com>; Kelly, Christopher J. <CKelly@mayerbrown.com>
Cc: Poonai, Alexander <apoonai@wsgr.com>; Johnson, Aaron <AJohnson@Taftlaw.com>; Jack Phillips <JCP@PMHDELaw.com>; Megan C. Haney <mch@PMHDELaw.com>; Dellinger, Megan E. <mdellinger@morrisnichols.com>; Raucci, Anthony D. <araucci@morrisnichols.com>
Subject: RE: Azurity Pharmaceuticals v. Bionpharma, Inc. [MB-AME.FID2745800]

[External]

Tina:

While we appreciate Azurity's apparent willingness to attempt make do with the page limits prescribed under the Delaware Local Rules, we still fail to understand why an 11-week briefing schedule for Azurity's purported forthcoming motion to dismiss is necessary, or even warranted, particularly in light of Azurity insistence on an expedited schedule and unjustifiable accusations of delay against Bionpharma, outlined below. It bears worth repeating one more time that the due date for the reply brief you're seeking to file will come **after** the close of fact discovery that Azurity vigorously advocated for during the parties' dispute over scheduling.

Nevertheless, in an effort to move past this dispute, and in consideration of your apparent willingness to (at least for now) make do with the page limits prescribed under the local rules, Bionpharma will agree to the briefing schedule you propose in your email from Monday. Please send over a draft stipulation for review.

- Roshan

From: Hanson, Tina <thanson@wsgr.com>
Sent: Monday, February 28, 2022 6:15 PM
To: Shrestha, Roshan P. <rshrestha@taftlaw.com>; Bank, Jeffrey <jbank@wsgr.com>; Alul, Andrew M. <AAAlul@taftlaw.com>; Kelly, Christopher J. <CKelly@mayerbrown.com>
Cc: Poonai, Alexander <apoonai@wsgr.com>; Johnson, Aaron <AJohnson@Taftlaw.com>; Jack Phillips <JCP@PMHDELaw.com>; Megan C. Haney <mch@PMHDELaw.com>; Dellinger, Megan E. <mdellinger@morrisnichols.com>; Raucci, Anthony D. <araucci@morrisnichols.com>
Subject: RE: Azurity Pharmaceuticals v. Bionpharma, Inc. [MB-AME.FID2745800]

[EXTERNAL MESSAGE]

Roshan,

Jeff is now out on paternity leave so I am stepping in and hopeful we can find some resolution here.

To start, it's a little disingenuous to stay that Bionpharma's First Motion to Dismiss complied with the Delaware briefing limits as that motion was filed in New Jersey and Bionpharma had 30 pages to brief with there. However, the drafting is ongoing. If the need for more pages persists, we understand your position and will take it up with the Court.

With respect to the timing, Bionpharma requested, and received, a trial schedule two years from now. I am a little surprised at your reticence to our request, given that we have repeatedly granted

Bionpharma's requests for extensions, even when it did not benefit Azurity because we believed the case should be expedited. We have continually operated in good faith in granting Bionpharma's requests and I am a little surprised at the lack of reciprocation but understand that this is the now the standard moving forward.

We do not agree with any of the characterizations below, but for the sake of brevity and with one last push to not burden the Court with an unnecessary motion, I would propose the following for the briefing schedule:

Opening Papers – March 24

Opposition – April 21

Reply – May 5

We make this offer with the understanding that, if Bionpharma rejects it, we are not waiving or prejudicing our right to move the Court with the original proposal.

Best,
Tina

Tina Hanson | Wilson Sonsini Goodrich & Rosati
One Market | Spear Tower | San Francisco, CA | 94105-1126 | direct: 415.947.2048 | thanson@wsgr.com

From: Shrestha, Roshan P. <rshrestha@taftlaw.com>
Sent: Sunday, February 27, 2022 12:18 PM
To: Bank, Jeffrey <ibank@wsgr.com>; Alul, Andrew M. <AAlul@taftlaw.com>; Kelly, Christopher J. <CJKelly@mayerbrown.com>
Cc: Poonai, Alexander <apoonai@wsgr.com>; Hanson, Tina <thanson@wsgr.com>; Johnson, Aaron <AJohnson@Taftlaw.com>; Jack Phillips <JCP@PMHDELaw.com>; Megan C. Haney <mch@PMHDELaw.com>
Subject: RE: Azurity Pharmaceuticals v. Bionpharma, Inc. [MB-AME.FID2745800]

[External]

Jeff:

Thanks for your email, and welcome to the “party,” as you describe it. We’ll excuse the misleading nature of your email (owing predominantly to the omission of numerous critical facts) based on your absence from most of the nearly five-and-a-half years the parties to this case have been litigating enalapril.

All of this “back-and-forth rhetoric,” as you characterize it, would be unnecessary, of course, had Azurity not adamantly pressed for an expedited schedule and repeatedly and unjustifiably accused Bionpharma of delay in these Third Wave Suits. While you accuse Bionpharma of seeking extensions on “four separate occasions,” you neglect to mention that two of those extensions had nothing to do with Bionpharma’s answers and counterclaims in the Third Wave Suits. Moreover, your assertion that Bionpharma had “essentially 7 months to draft and file its answer,” is also incorrect for several reasons,

including because for several of those months the parties were tied up briefing Bionpharma’s second motion to dismiss, necessitated by Azurity’s sham suits against its corporate sister (CoreRx) and subsequent voluntary dismissal of those suits. Also, Azurity did not file its First Amended and Supplemental Complaint in the 21-1286 action until November 11, 2021—a little over three months ago—how exactly was Bionpharma supposed to prepare its answer and counterclaims to that pleading before it was even filed? Your accusation regarding a one-week delay in providing Azurity with Bionpharma’s “trivial” redactions to Bionpharma’s pleadings from last Thursday rings incredibly hollow for obvious reasons. In any case, any extensions Bionpharma has sought pale in comparison to the numerous extensions Azurity has sought throughout these litigations—including an over 8-week extension that Azurity sought to get its opening brief on file in *its own* appeal of the First Wave Suits—and relentless delay tactics Azurity has employed in these cases (including a three-month delay caused by Azurity originally filing the 21-1286 action in the District of New Jersey to get away from Judge Stark’s adverse rulings in the First Wave Suits, and vigorously opposing a § 1404(a) motion Bionpharma filed to transfer the 21-1286 action back to Delaware where it belonged, going so far as to argue to the New Jersey court that the 21-1286 suit was not related to any pending enalapril litigations in Delaware (21-1286 D.I. 31, Azurity’s Opp’n to Def.’s Mot. to Transfer at 3-6), which Azurity knew was false (21-1286 D.I. 63, Sept. 14, 2021 Ltr. from. M. Dellinger to J. Cerino, Clerk of the Court (upon transfer, designating the 21-1286 action as related to other pending enalapril Delaware litigations)).

We simply find it hard to reconcile Azurity’s repeated accusations of delay and insistence on an expedited schedule for the Third Wave Suits with your desire to turn what would ordinarily be a 6-week briefing schedule into an extended 12-week schedule. Moreover, given His Honor’s imminent departure to the Federal Circuit, we believe Judge Stark will be less inclined to grant requests for extended briefing schedules (or additional brief pagination). We thus continue to believe that the schedule you propose for Azurity’s purported forthcoming motion to dismiss is excessive and simply unjustified, by Azurity’s own recent standards.

Nevertheless, in the interest of compromise, we are willing to agree to a 10 week briefing schedule for Azurity’s motion, with an agreed upon due date for Azurity’s reply, as follows:

1. March 17 – Motion to dismiss
2. April 14 – Opposition
3. April 28 – Reply

We propose the forgoing schedule as a fair compromise—should Azurity reject it, Bionpharma reserves the right to oppose any extension of the deadlines in place under the local rules.

Finally, we continue to believe that the parties should adhere to the local rules for page limitations. As mentioned above, in view of Judge Stark’s imminent departure, we believe His Honor will be less inclined than normal to accommodate additional page requests. And although the briefing on Bionpharma’s previous motions to dismiss concerned, as you say, only “patent issues,” they were nevertheless extensive and Bionpharma could easily have benefited from extra pages then (e.g., in connection with Bionpharma’s First Motion to Dismiss, Bionpharma had to address in meticulous detail why all 20 claims of the ‘023 patent were patentably indistinct from the claims of the First and Second Wave Patents, including with claim charts). Moreover, outside of the motion to dismiss context, the parties have complied with the Delaware local rule page limits; including in connection with Azurity’s PI motion in the First and Second Wave Suits, which involved not just patent issues, but also irreparable harm, balance of hardships, and public policy issues. See, e.g., 18-1962 D.I. 232, Silvergate’s Opening Br. in Supp. of Its Mot. for Prelim. Inj. Thus, we continue to see no reason why the parties cannot abide by the local rules for page limitations in connection with Azurity’s purported forthcoming motion to dismiss.

Thanks.

- Roshan

From: Bank, Jeffrey <jbanks@wsgr.com>
Sent: Thursday, February 24, 2022 3:22 PM
To: Shrestha, Roshan P. <rshrestha@taftlaw.com>; Alul, Andrew M. <AAlul@taftlaw.com>; Kelly, Christopher J. <CJKelly@mayerbrown.com>
Cc: Poonai, Alexander <apoonai@wsgr.com>; Hanson, Tina <thanson@wsgr.com>; Johnson, Aaron <AJohnson@Taftlaw.com>; Jack Phillips <JCP@PMHDELaw.com>; Megan C. Haney <mch@PMHDELaw.com>
Subject: Re: Azurity Pharmaceuticals v. Bionpharma, Inc. [MB-AME.FID2745800]

[EXTERNAL MESSAGE]

Roshan,

Thanks for your email. I'm relatively new to the party, and I reached out to Chris to try to avoid back-and-forth rhetoric. I thought my proposal was uncontroversial, and we wouldn't need to waste time on this.

But, your response surprised us. I understand that Bion has requested and received extensions on four separate occasions (Dkt. 94, 95, 108, and 130) and that Bion has had essentially 7 months to draft and file its answer. Additionally, Bion took a week to make trivial redactions to three paragraphs in its counterclaim, which prevented our client from reviewing the claims during that time. Moreover, given that Bion's proposed case schedule was largely adopted, and there will be a transition to a new judge, the proposed briefing schedule prejudices no one.

In light of those facts, so we can get on to the merits, can we agree to the following:

1. March 31 – Motion to dismiss (25 pages)
2. April 28 – Opposition (25 pages)
3. May 12 – Reply (15 pages)

Regarding the pages, my understanding is that previous briefing concerned only patent issues; this briefing will concern patent and antitrust issues, so a minor expansion of pages makes sense. I believe Bion previously made representations about the material impact of adding antitrust issues to the litigation. However, we are willing to reduce our proposal from 30 pages to 25 pages for the opening and opposition briefs. Regarding the reply, it doesn't make sense to leave the schedule open-ended, so we propose a set date.

Let me know if you want to discuss.

Regards,
Jeff

From: "Shrestha, Roshan P." <rshrestha@taftlaw.com>
Date: Thursday, February 24, 2022 at 11:30 AM
To: "Alul, Andrew M." <AAlul@taftlaw.com>, "Kelly, Christopher J." <CJKelly@mayerbrown.com>, Jeffrey Bank <jbanks@wsgr.com>
Cc: "Poonai, Alexander" <apoonai@wsgr.com>, "Hanson, Tina" <thanson@wsgr.com>,

"Johnson, Aaron" <AJohnson@Taftlaw.com>, Jack Phillips <JCP@PMHDELaw.com>, "Megan C. Haney" <mch@PMHDELaw.com>

Subject: RE: Azurity Pharmaceuticals v. Bionpharma, Inc. [MB-AME.FID2745800]

[External]

Counsel:

We are somewhat surprised by Azurity's proposal for a three-week extension of the time it needs to respond to Bionpharma's counterclaims, particularly in view of the accusations of delay Azurity made against Bionpharma during the dispute over scheduling for the Third Wave Suits and Azurity's insistence that an expedited schedule—with fact discovery closing on April 25, 2022, before briefing on Azurity's purported forthcoming motion to dismiss would even be completed, under Azurity's proposal—was warranted, irrespective of the scope of Bionpharma's counterclaims. *See, e.g.,* 21-1286 D.I. 117, Azurity's Jan. 19, 2022 Ltr. at 1-2.

Nevertheless, Bionpharma is open to stipulating to a reasonable extension of the time Azurity needs to respond to Bionpharma's counterclaims in the Third Wave Suits, but three weeks seems excessive, particularly in view of Azurity's positions during the scheduling dispute. *See also* February 7, 2022 email from T. Hanson to R. Shrestha ("Azurity agrees to a one-week extension for Bionpharma's response to Azurity's complaint, ***but will not agree to any further extensions beyond this.***" (emphasis added)).

In view of the foregoing, Bionpharma will agree to a two-week extension of the current deadline (March 10, 2022) for Azurity to respond to Bionpharma's counterclaims, or until March 24, 2022, provided that Azurity will agree to extend the due date for Bionpharma's response to Azurity's purported forthcoming motion to dismiss until April 21, 2022. We believe the parties should wait until Bionpharma has responded to Azurity's motion before discussing any extension of the due date for Azurity's reply.

With respect to page limits, we believe the parties should follow the local rules, which, of course, is what the parties did in connection with Bionpharma's previous motions to dismiss (21-1286 D.I. 8, 97).

Thanks.

- Roshan

Taft / Roshan P. Shrestha, Ph.D.

Partner

rshrestha@taftlaw.com

Dir: 312.840.4339

Tel: 312.527.4000 | Fax: 312.966.8573

111 E. Wacker Drive, Suite 2800

Chicago, Illinois 60601-3713

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From: Alul, Andrew M. <AAlul@taftlaw.com>
Sent: Tuesday, February 22, 2022 3:38 PM
To: Kelly, Christopher J. <CJKelly@mayerbrown.com>; Bank, Jeffrey <jbank@wsgr.com>
Cc: Poonai, Alexander <apoonai@wsgr.com>; Hanson, Tina <thanson@wsgr.com>; Shrestha, Roshan P. <rshrestha@taftlaw.com>; Johnson, Aaron <AJohnson@Taftlaw.com>
Subject: RE: Azurity Pharmaceuticals v. Bionpharma, Inc. [MB-AME.FID2745800]

Copying Roshan Shrestha and Aaron Johnson—please also include them on all further correspondence for this matter, regardless of whether the communication pertains to Bionpharma's antitrust counterclaim or otherwise.

Thanks.

- Andy

Taft / **Andrew M. Alul**, Partner
Litigation; Intellectual Property/Patent
Direct: 312.836.4135 | Office Ext: 34135
Taft Office: Chicago

From: Kelly, Christopher J. <CJKelly@mayerbrown.com>
Sent: Tuesday, February 22, 2022 3:30 PM
To: Bank, Jeffrey <jbank@wsgr.com>; Alul, Andrew M. <AAlul@taftlaw.com>
Cc: Poonai, Alexander <apoonai@wsgr.com>; Hanson, Tina <thanson@wsgr.com>
Subject: RE: Azurity Pharmaceuticals v. Bionpharma, Inc. [MB-AME.FID2745800]

[EXTERNAL MESSAGE]

Good to hear from you, Jeff. Let me bring Andy Alul, whom you all know, into the conversation. We'll be back to you.

Best regards.

Chris

From: Bank, Jeffrey <jbank@wsgr.com>
Sent: Tuesday, February 22, 2022 1:23 PM
To: Kelly, Christopher J. <CJKelly@mayerbrown.com>
Cc: Poonai, Alexander <apoonai@wsgr.com>; Hanson, Tina <thanson@wsgr.com>
Subject: Azurity Pharmaceuticals v. Bionpharma, Inc.

****EXTERNAL SENDER****

Hi Chris,

Hope you're well. I'm writing with regards to the answer/counterclaim filed by Bion. We'd like to discuss an appropriate briefing schedule for a motion to dismiss. In light of the previous extensions granted and the extent of the allegations in the counterclaims, we would propose the following:

March 31 – Motion to dismiss (30 pages)
April 28 – Opposition (30 pages)
May 12 – Reply (15 pages)

Let me know if you want to discuss. We can draft a stipulation if you agree.

Thanks,
Jeff

Jeff Bank | Partner | Wilson Sonsini Goodrich & Rosati
1700 K Street NW | Washington, DC 20006 | direct: 212.497.7761 | mobile: 607.262.0211 | jbank@wsgr.com

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EXHIBIT D

TABLE OF PENDING BIONPHARMA REQUESTS SEEKING ANTITRUST DISCOVERY**Bionpharma's First Set of Requests for Production of Documents and Things**

RFP No.	Request	Relates to
11	Documents sufficient to show the ownership interest of NovaQuest in Azurity and CoreRx.	CoreRx Suits
12	Documents sufficient to show organizational structure of, and corporate relationship between, Azurity, NovaQuest, and CoreRx.	CoreRx Suits
13	Documents sufficient to show the ownership of Azurity, NovaQuest, and CoreRx.	CoreRx Suits
14	All documents and things concerning relationships, agreements, and communications between Azurity and either NovaQuest or CoreRx or both (or any affiliate or subsidiary thereof) as they relate to the Enalapril Liquid Patents, Related Patent Applications, Epaned, and/ or NDA No. 208686.	CoreRx Suits
15	Any settlement agreements between Azurity and either NovaQuest or CoreRx or both (or any affiliate or subsidiary thereof) as they relate to Enalapril Liquid Patents, Related Patent Applications, Epaned, and/or NDA No. 208686.	CoreRx Suits
19	All documents and things referring or relating to any valuations of the indemnification granted by Azurity to CoreRx in the settlement agreement between Azurity and CoreRx regarding Third Wave Patents.	CoreRx Suits
20	All documents and things concerning the Azurity-CoreRx LSA, including any drafts of the Azurity-CoreRx LSA.	CoreRx Suits
21	All documents and communications relating to actual or potential generic competition to Epaned.	Antitrust Issues
22	All documents and communications with NovaQuest relating to Bionpharma, Bionpharma's ANDA Product, or any actual or potential competition to Epaned.	CoreRx Suits
23	All documents and communications with NovaQuest relating to CoreRx's relationship with Bionpharma, including documents and communications pertaining to the MMSA.	CoreRx Suits
24	All documents and communications with CoreRx relating to generic competition	CoreRx Suits

RFP No.	Request	Relates to
	to Epaned, the Enalapril Liquid Patents, Bionpharma's ANDA Product, the MMSA, the Azurity-CoreRx LSA, NovaQuest, and any other enalapril ANDA filer.	
25	All documents and communications relating to generic competition to Epaned, the Enalapril Liquid Patents, Bionpharma's ANDA Product, CoreRx, the Azurity-CoreRx LSA, NovaQuest, and any other ANDA filer, to or from any board member, past or present, of CoreRx, including Messrs. Nailesh Bhatt, Vern Davenport, IV Jeff Edwards, and Frank Leo.	CoreRx Suits
26	All documents and communications relating to generic competition to Epaned, the Enalapril Liquid Patents, Bionpharma's ANDA Product, CoreRx, the Azurity-CoreRx LSA, NovaQuest, and any other ANDA filer, to or from any board member, past or present, of Azurity, including Messrs. Nailesh Bhatt, Richard Blackburn, Vern Davenport, Jeff Edwards, Frank Leo, Amit Patel, and Dave Ritchie.	CoreRx Suits
27	All documents and things, including communications between Azurity and NovaQuest, relating to NovaQuest's decision, negotiation, or agreement to take an ownership interest in CoreRx.	CoreRx Suits
28	All documents, communications, and things relating to Azurity's decision to sue CoreRx for alleged infringement of Third Wave Patents.	CoreRx Suits
29	All documents, communications, and things between Azurity and NovaQuest relating to Azurity's decision to sue CoreRx for alleged infringement of Third Wave Patents.	CoreRx Suits
30	All documents and things pertaining to Azurity's decision to voluntarily dismiss <i>Azurity Pharmaceuticals, Inc. v. CoreRx, Inc.</i> , C.A. No. 21-1522-LPS (D. Del.) and <i>Azurity Pharmaceuticals, Inc. v. CoreRx, Inc.</i> , C.A. No. 21-2515-VMC-SPF (M.D. Fla.).	CoreRx Suits
40	All documents and communications (including from consultants, market analysts, attorneys, or other third parties), including any opinions of counsel, concerning the strength(s) or weakness(es) of any of the Enalapril Liquid Patents and/or the merits or expected outcome of any of the First Wave Suits, Second Wave Suit, Third Wave Suits and/or Related Patent Litigations.	First Wave Suits
41	All documents and things concerning any opinions of counsel concerning any of the Enalapril Liquid Patents, the First Wave Suits, the Second Wave Suit, the Third Wave Suits, and/or Related Patent Litigations.	First Wave Suits

RFP No.	Request	Relates to
44	Documents sufficient to identify each drug that competes with Epaned.	Antitrust Issues
45	Documents sufficient to identify each hypertension treatment that competes with Epaned.	Antitrust Issues
46	Documents sufficient to identify each symptomatic heart failure treatment that competes with Epaned.	Antitrust Issues
47	Documents sufficient to identify each asymptomatic left ventricular dysfunction treatment that competes with Epaned.	Antitrust Issues
48	Documents sufficient to describe the cost, availability, and distribution of any product or treatment that competes with Epaned or is used to treat hypertension, symptomatic heart failure, and/or symptomatic heart failure.	Antitrust Issues
49	All documents and things relating to the gross and net sales, market share, gross and net profits; sales and profit forecasts; advertising, promotion, presentation, description, and/or explanation of any product or treatment that competes with Epaned or is used to treat hypertension, symptomatic heart failure, and/or symptomatic heart failure.	Antitrust Issues
53	All documents relating to any market in which Epaned competes, including all documents relating to the market share of Epaned and/or any product or therapy that actually or potentially competes with Epaned, any competitive analysis of any product or therapy that actually or potentially competes with Epaned, and the impact (including impact on sales (in dollars or unit volume) and/or profits) on Azurity of any product or therapy that actually or potentially competes with Epaned.	Antitrust Issues
57	Any market research, physician surveys, or prescriptions data analysis for Epaned or for any treatment that competes with Epaned or that is used to treat hypertension, symptomatic heart failure, and/or symptomatic heart failure.	Antitrust Issues
62	All documents and communications relating to generic competition to Epaned, including evaluation of ANDA filers.	Antitrust Issues
63	All documents concerning competition for the sale of any enalapril product.	Antitrust Issues
64	All documents, communications, and things relating to Azurity's decision to sue, and/or to maintain any suit against, Bionpharma for alleged infringement of First Wave Patents, including:	First Wave Suits

RFP No.	Request	Relates to
	<p>a. All documents, communications, and things relating to the merits of Azurity's claims, including whether any objective basis exists for them.</p> <p>b. All documents, communications, and things relating to the likelihood that Azurity would obtain any relief on its claims;</p> <p>c. All documents, communications, and things relating to Azurity's legal and business objectives from asserting the claims, including the effect of this and/or other patent litigations on Bionpharma's financial ability and/or willingness to defend against the claims; and</p> <p>d. All documents, communications and things relating to the effect of Azurity's suing, or maintaining any suit, against Bionpharma for alleged infringement of First Wave Patents, including any effect on Azurity's sales (in dollars or unit volume) or profit margins for Epaned.</p>	
65	<p>All documents, communications, and things relating to Azurity's decision to sue, and/or to maintain any suit against, Bionpharma for alleged infringement of Second Wave Patents, including:</p> <p>a. All documents, communications, and things relating to the merits of Azurity's claims, including whether any objective basis exists for them.</p> <p>b. All documents, communications, and things relating to the likelihood that Azurity would obtain any relief on its claims;</p> <p>c. All documents, communications, and things relating to Azurity's legal and business objectives from asserting the claims, including the effect of this and/or other patent litigations on Bionpharma's financial ability and/or willingness to defend against the claims; and</p> <p>d. All documents, communications and things relating to the effect of Azurity's suing, or maintaining any suit, against Bionpharma for alleged infringement of Second Wave Patents, including any effect on Azurity's sales (in dollars or unit volume) or profit margins for Epaned.</p>	Antitrust Issues

Bionpharma's First Set of Interrogatories

No.	Interrogatory	Relates to
4	Describe in detail the relationship between Azurity, NovaQuest, and CoreRx, including any ownership interest that NovaQuest has in Azurity and/or CoreRx, and the extent of such ownership interest.	CoreRx Suits

EXHIBIT E

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

BIONPHARMA INC.,

Plaintiff,

v.

CORERX, INC.,

Defendant.

CORERX, INC.,

Counterclaim-Plaintiff,

v.

BIONPHARMA, INC.,

Counterclaim-Defendant.

Case No. 21-cv-10656 (JGK)

**DEFENDANT CORERX, INC.’S
ANSWER TO COMPLAINT WITH
AFFIRMATIVE DEFENSES AND
COUNTERCLAIMS**

Defendant CoreRx, Inc. (“Defendant” or “CoreRx”), by and through its undersigned counsel, Buchanan Ingersoll & Rooney PC, respectfully submits this Answer with Affirmative Defenses and Counterclaims to the Complaint of Plaintiff Bionpharma Inc. (“Plaintiff” or “Bionpharma”) filed on December 13, 2021 (ECF No. 1) (the “Complaint” or “Compl.”), and asserts as follows:

THE PARTIES¹

1. CoreRx denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 1.
2. CoreRx admits the allegations in paragraph 2.

¹ CoreRx herein copies the section headings used in the Complaint for ease of reference only; the headings do not constitute part of CoreRx’s answer to the allegations of the Complaint. To the extent that answers to the Complaint’s section headings may be required, CoreRx hereby denies all such headings.

JURISDICTION AND VENUE

3. CoreRx admits that this action involves a dispute between citizens of different states, but otherwise denies the allegations in paragraph 3 and states that no response is required to the legal conclusions contained therein.

4. CoreRx states that paragraph 4 contains legal conclusions to which no response is required. To the extent a response is required, CoreRx admits that it was party to the referenced Agreement² attached as Exhibit A to the Complaint, states that the Agreement speaks for itself, and refers the Court to the Agreement for its terms.

5. CoreRx states that paragraph 5 contains legal conclusions to which no response is required. To the extent a response is required, CoreRx admits that it was party to the Agreement, states that the Agreement speaks for itself, and refers the Court to the Agreement for its terms.

BACKGROUND

6. CoreRx admits that it entered into the Agreement with CoreRx in November 2020, acknowledges that the attached Exhibit A to the Complaint appears to be a true, accurate and complete copy of that Agreement, states that the Agreement speaks for itself, and refers the Court to the Agreement for its terms.

7. CoreRx denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 7.

8. CoreRx denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 8.

² Unless otherwise specified herein, abbreviations and capitalized terms have the meanings ascribed to them in the Complaint.

9. CoreRx states that paragraph 9 contains legal conclusions to which no response is required and, to the extent a response is required, CoreRx denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 9.

10. CoreRx admits that Silvergate was the predecessor to Azurity and that Azurity holds the marketing authorization for Epaned, but otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 10.

11. CoreRx admits that Silvergate brought a patent infringement suit against Bionpharma in the U.S. District Court for the District of Delaware (“Delaware District Court”) in December 2018, and that Azurity brought a separate patent infringement suit against Bionpharma in the Delaware District Court on September 18, 2020, but otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 11 and states that no response is required to the legal conclusions contained therein.

12. CoreRx admits that Azurity filed a new patent infringement suit against Bionpharma in June 2021 in the U.S. District Court for the District of New Jersey; that Azurity therein filed a motion for preliminary injunction, which Bionpharma opposed; that, while the preliminary injunction motion was pending, the suit was transferred to the Delaware District Court; that the Delaware District Court denied Azurity’s preliminary injunction motion on November 10, 2021; and that that lawsuit remains pending. CoreRx further admits that Azurity initiated another new, separate patent infringement suit against Bionpharma in the District of Delaware on October 15, 2021, and that that suit too remains pending. As to any and all remaining allegations in paragraph 12, CoreRx denies knowledge or information sufficient to form a belief as to the truth of those allegations and states that no response is required to the legal conclusions contained therein.

13. CoreRx admits that Azurity commenced two separate patent infringement lawsuits against CoreRx in October 2021 (one in the District of Delaware and one in the U.S. District Court for the Middle District of Florida), both predicated upon allegations that CoreRx's actions in manufacturing the Product for Bionpharma infringed two of Azurity's existing patents (the "Azurity-CoreRx Lawsuits"). As to any and all remaining allegations in paragraph 13, CoreRx denied knowledge or information sufficient to form a belief as to the truth of those allegations and states that no response is required to the legal conclusions contained therein.

14. CoreRx admits that on or about November 26, 2021, Azurity dismissed the Azurity-CoreRx Lawsuits, but otherwise denies the allegations in paragraph 14 and avers that the dismissals of both of the Azurity-CoreRx Lawsuits were dismissals without prejudice.

15. CoreRx denies the allegations in paragraph 15 and states that no response is required to the legal conclusions contained therein.

16. CoreRx states that no response is required to the allegations in paragraph 16 because they set forth Bionpharma's characterization or interpretation of the Agreement, which speaks for itself, and denies any allegations inconsistent therewith. To the extent a response to the allegations in paragraph 16 is required, CoreRx denies knowledge or information sufficient to form a belief as to the truth of those allegations.

17. CoreRx admits the allegations in paragraph 17.

18. CoreRx admits that Bionpharma responded to the fax referenced in paragraph 17 of the Complaint and attached as Exhibit B thereto; admits that the attached Exhibit C to the Complaint appears to be a true, accurate and complete copy of said response; and states that Exhibit C speaks for itself. To the extent a further response to paragraph 18 is required, CoreRx admits that Bionpharma, in its response, made a contention that CoreRx was in breach of the Agreement,

but does not admit, and rather denies, the substance of that contention, and denies the remainder of the allegations in paragraph 18 as well.

19. CoreRx admits that Bionpharma placed an order with CoreRx for a specified quantity of Product on or about August 26, 2021 and that the attached Exhibit D to the Complaint appears to be a true, accurate and complete copy of said order (the “August 26 Firm Order”), but otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 18.

20. CoreRx states that no response is required to the allegations in paragraph 20 because they set forth Bionpharma’s characterization or interpretation of the requirements and terms of the Agreement, which speaks for itself, and denies any allegations inconsistent therewith. To the extent a response to the allegations in paragraph 20 is required, CoreRx denies knowledge or information sufficient to form a belief as to the truth of those allegations.

21. CoreRx denies the allegations in paragraph 21, and further avers that, pursuant to the Preliminary Injunction entered by the Court in this action on February 4, 2022 (ECF No. 79) (the “Preliminary Injunction”), CoreRx has manufactured, and Bionpharma has taken possession of, 100% of the Product ordered in the August 26 Firm Order.

22. CoreRx admits that, as of the date the Complaint was filed, it had advised Bionpharma that it did not intend to manufacture or ship to Bionpharma the then-unfilled portion of the August 26 Firm Order, but states that, pursuant to the Preliminary Injunction, CoreRx had as of March 4, 2022 manufactured and shipped Product to Bionpharma in accordance with the August 26 Firm Order.

23. CoreRx admits that it entered into an agreement with Azurity that relates to the Product, and that CoreRx and Azurity are entities that are under private equity control (albeit under

control by two different private equity funds), and otherwise denies the allegations of the introductory portion of paragraph 23, and responds to the various, additional subparts of paragraph 23 as follows:

- a. CoreRx denies the allegations in paragraph 23(a), and avers that in January 2021, a majority of the stock of CoreRx was acquired by a fund affiliated with NovaQuest Capital Management (together with its affiliates, “NovaQuest”).
- b. CoreRx denies the allegations in paragraph 23(b), and avers that it is two different private equity funds affiliated with NovaQuest that have controlling interests in, respectively, CoreRx and Azurity;
- c. CoreRx admits that CoreRx’s board of directors (the “CoreRx Board”) has seven members, and that certain of those seven members of the CoreRx Board also have positions or affiliations with NovaQuest, but otherwise denies the allegations of paragraph 23(c), and specifically as to its subparts, further as alleges as follows:
 1. CoreRx denies that Frank Leo is the chairman of the board of directors of Azurity (the “Azurity Board”), but admits that Mr. Leo is a member of the Azurity Board, and avers that Amit Patel is the current Executive Chairman of the Azurity Board. CoreRx admits the remaining allegations in paragraph 23(c)(1).
 2. CoreRx admits the allegations in paragraph 23(c)(2).
 3. CoreRx denies knowledge or information sufficient to form a belief as to the truth of paragraph 23(a)(c)(3)’s allegations that Jeff

Edwards is a founder and an investment committee member at NovaQuest, but admits that Mr. Edwards is affiliated with NovaQuest, albeit in a manner that is unknown to CoreRx. CoreRx admits the remaining allegations in paragraph 23(c)(3).

4. CoreRx denies that Ashton Poole is a member of the Azurity Board, but otherwise admits the allegations in paragraph 23(c)(4).
5. CoreRx admits the allegations in paragraph 23(c)(5).

d. CoreRx restates and incorporates by reference its responses stated in the preceding paragraph 23(c) and subparts (1) through (5) thereof, and further admits that the Azurity Board is constituted of seven (7) members and that a majority of the current Azurity Board members “overlap” and form a majority of the current CoreRx Board. CoreRx denies the remaining allegations in paragraph 23(d), and avers that only four (4) members of the current CoreRx Board are “Overlapping Directors” who also serve on the current Azurity Board.

e. CoreRx admits that Ajay Damani became CoreRx’s CEO and a member of the CoreRx Board in October 2021, but otherwise denies the allegations in paragraph 23(e) and avers that Mr. Damani had, prior to his joining CoreRx, been a Strategic Advisor with a particular NovaQuest affiliate, NovaQuest Capital Management, LLC.

f. CoreRx admits that the fax stating that CoreRx would no longer supply Product to Bionpharma was sent on November 30, 2021, and that the stipulation of dismissal in the second of the two Azurity-CoreRx Lawsuits

was filed on November 26, 2021, and states that no response is required to the remaining allegations in paragraph 23(f) because they set forth only Bionpharma's conclusions and not any facts. To the extent a response to the remaining allegations in paragraph 23(f) is required, CoreRx denies the allegations.

- g. CoreRx admits the allegations in paragraph 23(g).
- h. CoreRx avers that two separate and distinct funds affiliated with NovaQuest own controlling percentages of the stock of, respectively, CoreRx and Azurity, and that certain members of the CoreRx Board also serve on the Azurity Board, but denies any further relation between CoreRx and Azurity, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 23(h).
- i. CoreRx denies the allegations in paragraph 23(i).
- j. CoreRx admits that on November 19, 2021, CoreRx proposed to Bionpharma a price increase for the Product to be applied in the coming year but denies said proposed increase was "substantial." CoreRx also admits that the parties had negotiated the then-existing price one year prior, in November 2020. CoreRx denies the remaining allegations in paragraph 23(j).
- k. CoreRx denies the allegations in paragraph 23(k).
- l. CoreRx states that no response is required to the allegations in paragraph 23(l) because they set forth Bionpharma's interpretation of terms of the Agreement, which speaks for itself, and denies any allegations inconsistent

therewith. To the extent a response to the allegations in paragraph 23(l) is required, CoreRx denies the allegations.

COUNT 1 – BREACH OF CONTRACT

24. CoreRx restates and incorporates by reference its responses stated in the preceding paragraphs 1 through 23 as if fully set forth herein.
25. CoreRx denies the allegations in paragraph 25.
26. CoreRx denies the allegations in paragraph 26.
27. CoreRx denies the allegations in paragraph 27.
28. CoreRx states that paragraph 28 contains legal conclusions to which no response is required and, to the extent a response is required, CoreRx denies knowledge and information sufficient to form a belief as to the truth of the allegations in paragraph 28.
29. CoreRx denies knowledge and information sufficient to form a belief as to the truth of the allegations in paragraph 29.
30. CoreRx denies the allegations in paragraph 30.

COUNT 2 – DECLARATORY JUDGMENT

31. CoreRx restates and incorporates by reference its responses stated in the preceding paragraphs 1 through 30 as if fully set forth herein.
32. CoreRx states that paragraph 32 contains legal conclusions to which no response is required. To the extent a response to the allegations in paragraph 32 is required, CoreRx denies the allegations and avers that Bionpharma is entitled to no relief whatsoever from CoreRx.

RESPONSE TO PRAYER FOR RELIEF

To the extent a response is required to the section of the Complaint titled “Prayer for Relief” (see Compl. at 9), CoreRx denies that Bionpharma is entitled to any relief, including, but not

limited to, the relief and/or demands set forth in paragraphs A through E of the Prayer for Relief.

AFFIRMATIVE DEFENSES

To the extent CoreRx has not expressly admitted any allegations here, such allegations are denied. CoreRx reserves its right to amend its Answer with Counterclaims and Affirmative Defenses to the extent it learns additional information regarding the allegations set forth in Bionpharma's Complaint.

CoreRx pleads the following Affirmative Defenses in response to the Complaint. CoreRx does not knowingly or intentionally waive any applicable defense, and reserves the right to assert and rely on such other applicable defenses as may become available or apparent during the course of the proceedings. CoreRx further reserves its right to amend its Answer with Counterclaims and Affirmative Defenses accordingly, and/or to delete affirmative defenses that it determines are not applicable, during the course of the proceedings. By asserting the following affirmative defenses, CoreRx does not concede it has the burden of proof, or any other burden, with respect to any of them:

FIRST AFFIRMATIVE DEFENSE

The Complaint, in whole or in part, fails to state a claim upon which relief may be granted or for which the relief or recovery sought can be awarded to Plaintiff.

SECOND AFFIRMATIVE DEFENSE

The Complaint, and each cause of action pleaded therein, is preempted by one or more statutes, rules, standards and/or regulations of the United States government including, but not limited to, the federal Patent Act, 35 U.S.C. §§ 1 *et seq.*

THIRD AFFIRMATIVE DEFENSE

Defendant's performance under the Agreement was excused pursuant to the doctrine of frustration of purpose.

FOURTH AFFIRMATIVE DEFENSE

Defendant's performance under the Agreement was excused pursuant to the doctrine of commercial impracticability.

FIFTH AFFIRMATIVE DEFENSE

Defendant's performance under the Agreement was excused as a result of impossibility of performance.

SIXTH AFFIRMATIVE DEFENSE

Plaintiff's purported claims are barred, in whole or in part, by the equitable doctrines of waiver, estoppel, unclean hands, unjust enrichment, laches, mistake and/or other related equitable doctrines.

SEVENTH AFFIRMATIVE DEFENSE

Plaintiff's purported claims are barred, in whole or in part, by the terms, conditions, provisions and limitations of the Agreement.

EIGHTH AFFIRMATIVE DEFENSE

Plaintiff's purported claims are barred, in whole or in part, by Plaintiff's failure to perform under the Agreement.

NINTH AFFIRMATIVE DEFENSE

Plaintiff's purported claims are barred, in whole or in part, by Plaintiff's breach of the implied covenant of good faith and fair dealing owed by Plaintiff to CoreRx.

TENTH AFFIRMATIVE DEFENSE

Plaintiff's purported claims are barred, in whole or in part, by virtue of Plaintiff not having held clear ownership, title or interest in the intellectual property that it licensed to Defendant under the parties' Agreement.

ELEVENTH AFFIRMATIVE DEFENSE

To the extent that Plaintiff suffered any damages, which damages are denied, any such damages are barred and/or must be reduced on account of Plaintiff's failure to take reasonable steps to mitigate damages.

TWELFTH AFFIRMATIVE DEFENSE

The Complaint is barred, in whole or in part, by any previous recovery for the same damages and/or harm alleged in the Complaint.

THIRTEENTH AFFIRMATIVE DEFENSE

To the extent any liability is established, Plaintiff's claims, in whole or in part, are subject to a setoff for quantities of Product that Defendant has already produced and delivered to Plaintiff pursuant to the Preliminary Injunction or otherwise.

FOURTEENTH AFFIRMATIVE DEFENSE

Plaintiff's purported claims are barred, in whole or in part, because Defendant at all times acted reasonably and in good faith in performing any and all obligations it owed to Plaintiff under the Agreement.

ADDITIONAL DEFENSES

Defendant reserves the right to assert additional defenses based on information learned or obtained during discovery or otherwise in the course of proceedings.

COUNTERCLAIMS³

Defendant and Counterclaim-Plaintiff CoreRx asserts counterclaims against Plaintiff and Counterclaim-Defendant Bionpharma for (i) breach of the implied contractual covenant of good faith and fair dealing and (ii) unjust enrichment, stating as follows:

PARTIES

1. Defendant and Counterclaim-Plaintiff CoreRx is a Florida corporation with its principal place of business in Clearwater, Florida.
2. Plaintiff and Counterclaim-Defendant Bionpharma is a Delaware corporation with its principal place of business in Princeton, New Jersey.

JURISDICTION AND VENUE

3. The Court has subject matter jurisdiction over CoreRx's counterclaims under 28 U.S.C. § 1332(a)(1) because the matter in controversy exceeds seventy-five thousand dollars (\$75,000.00) exclusive of interest and costs, and is between citizens of different states such that there is complete diversity between the parties, and under 28 U.S.C. § 1337(a) because the counterclaims are so related to Bionpharma's claims that they form part of the same case or controversy under Article III of the United States Constitution.

4. The Court has personal jurisdiction over Bionpharma because, pursuant to the parties' Agreement out of which CoreRx's counterclaims arise, Bionpharma expressly consented and submitted to personal jurisdiction in this Court in connection with any disputes arising out of or in connection with said Agreement, and because it is a business that conducts substantial

³ Consistent with the Order of this Court dated December 14, 2021 (ECF No. 21) and the parties' past practices in this action, CoreRx submits its Counterclaims and accompanying Exhibits under seal, given the inclusion of confidential pricing information and pricing terms. CoreRx submits contemporaneously herewith redacted versions for filing on the public docket, from which this information, but nothing else, has been redacted.

business in, and has and solicits shareholders in, this District and has thus availed itself to this District for jurisdictional purposes.

5. Venue is proper in this District pursuant to the parties' Agreement, in which Bionpharma and CoreRx consented to, and waived any objections to venue in this Court and agreed to not bring claims arising under the Agreement in any other court, and pursuant to 28 U.S.C. § 13391(b)(2), in that a substantial part of the events and transactions giving rise to CoreRx's counterclaims occurred in this District.

FACTUAL ALLEGATIONS

A. The Parties' Relationship, Complementary Business Expertise and Intention to Enter into Mutually Beneficial Business Arrangement Through the Agreement

6. CoreRx is a pharmaceutical contract development manufacturing organization ("CDMO") with sites in Clearwater, Florida and San Rafael, California. On behalf of its pharmaceutical customers, CoreRx manufactures clinical trial and commercial drug products, focusing mainly on oral solid and liquid products for distribution to the United States market.

7. Bionpharma is a company that, by partnering with pharmaceutical manufacturers such as CoreRx, seeks to develop and commercialize affordable quality generic drugs for profit. On information and belief, Bionpharma currently markets and distributes more than 33 generics in the United States for profit.

8. CoreRx and Bionpharma began doing business together in or around 2017. During the course of the parties' relationship, CoreRx has manufactured various generic pharmaceutical products for Bionpharma, which Bionpharma has proceeded to market and distribute to the public for a profit.

9. On or about November 24, 2020, CoreRx and Bionpharma entered into that same Master Manufacturing Supply Agreement (or “Agreement”) that forms the basis of the allegations and claims in Bionpharma’s Complaint and which Bionpharma attached as Exhibit A thereto. A true and accurate copy of the Agreement, with select nonpublic financial terms having been redacted, is also attached as Exhibit 1 to the within Counterclaims.

10. The parties’ purpose in entering into the Agreement was to form a mutually beneficial business relationship under which, pursuant to their respective areas of expertise, CoreRx would manufacture and supply for Bionpharma certain generic pharmaceutical products that Bionpharma had developed, so that Bionpharma could then market and distribute the products downstream. Under the Agreement, Bionpharma agreed to pay CoreRx for its manufacture and supply of products covered thereunder.

11. One of the products that the parties agreed to be covered by the Agreement was enalapril maleate oral liquid solution product (referenced herein, consistent with Bionpharma’s Complaint, as simply the “Product”), which is a generic version of the branded drug Epaned®, which is produced by Azurity Pharmaceuticals, Inc. (“Azurity”).

12. At the time the parties entered into the Agreement in November of 2020, they were connected beyond just their approximately four-year history of business dealings together.

13. At that time and all relevant times herein, a private equity fund, Signet Healthcare Partners (together with its affiliated funds and other affiliates, “Signet”) or one of its affiliates owned a controlling stake in Bionpharma. At that time, up through January of 2021, Signet also held an approximate 17% stake in CoreRx, as well.

14. As a result, when the Agreement was being negotiated and executed, up through January of 2021, certain members of Bionpharma's management and its board of directors (the "Bionpharma Board") also sat on CoreRx's board of directors (the "CoreRx Board").

15. Indeed, for the relevant time period, the same individual—James Gale, the founding partner of Signet—served as the Chairperson of the Bionpharma Board *and* the Chairperson of the CoreRx Board. Mr. Gale is the founding partner of Signet.

16. Additionally, during all relevant times herein through January 2021, Bionpharma's President and Chief Executive Officer, Venkat Krishnan, and its Chief Financial Officer and Executive Vice President of Operations, Guarav Mehrota, served on the CoreRx Board. Mr. Krishnan has at all relevant times herein also been a member of the Bionpharma Board.

17. While CoreRx was an experienced CDMO by the time the parties began to contemplate CoreRx being the manufacturer of the Product at issue and negotiating the Agreement, in or around mid-2020, its experience was up until then limited to clinical drug manufacturing. CoreRx did not have any experience at that time in commercial drug manufacturing, as is contemplated under the Agreement with respect to the Product.

18. Clinical drug manufacturing and commercial drug manufacturing are very different processes, for numerous reasons. In the case of commercial manufacturing, a CDMO such as CoreRx is making product in mass amounts to be sold to the market on a mass scale. A pharmaceutical product that is being manufactured for commercial use has gone through the required regulatory approvals, and the manufacturer is operating on a large scale to turn out hundreds lots of product, striving for standardization and limited to no variance across each unit and lot of product produced.

19. On the other hand, clinical drug manufacturing occurs at an earlier stage in the product lifestyle, while the product is still undergoing the requisite testing and regulatory and agency approval processes. As such, in clinical manufacturing, each lot of product produced is unique, as the process and exact specifications are constantly changing and evolving to meet the desired testing and regulatory thresholds required before the drug can be commercially produced and sold to the public. Commercial production is, among other things, far more automatized and “scaled up” than clinical manufacturing.

20. Given CoreRx’s total inexperience up in commercial manufacturing at the time it was negotiating the Agreement with Bionpharma, its management team did not have the experience or know-how to accurately forecast the added costs and overhead that it would incur in manufacturing a product for commercial purposes, as required under the Agreement, and was generally unsophisticated when it came to the additional requirements that commercial manufacturing would impose upon the company. Given this lack of experience and knowledge, CoreRx and its management team was heavily dependent upon the CoreRx Board to represent CoreRx and guide it through the decision-making and negotiations with respect to a potential deal with Bionpharma relating to the Product.

21. As noted above, at the time, the CoreRx Board, which by virtue of CoreRx’s inexperience in commercial manufacturing played a major role in negotiating the Agreement with Bionpharma, was chaired by James Gale, who was concurrently chairing the Bionpharma Board, and also included several key members of Bionpharma’s executive leadership team.

22. One of the key pieces of the negotiation was the price that Bionpharma was to pay CoreRx for each unit of Product produced, especially given that, as alleged previously herein, both

parties had the intention that the Agreement memorialize a business transaction that was mutually beneficial and profitable for both sides.

23. CoreRx relied upon the members of the CoreRx Board to advise CoreRx as to whether to accept or reject prices proposed by Bionpharma, so as to assure that CoreRx was paid a per-bottle price for the Product sufficient to cover CoreRx's per-bottle manufacturing costs, and also represent a [REDACTED]

[REDACTED]

[REDACTED]

24. The members of the CoreRx Board had full knowledge that CoreRx only desired to enter into the Agreement with Bionpharma if the arrangement would result in CoreRx being paid a unit price that was high enough to translate into [REDACTED] for CoreRx.

25. Armed with that knowledge, the CoreRx Board, including members of the Bionpharma Board and Bionpharma's leadership team, advised CoreRx to accept a unit price of [REDACTED] per bottle (the "Unit Price"). CoreRx, in reliance on the CoreRx Board for critical guidance given its utter lack of prior experience in commercial drug manufacturing, listened and, accordingly, executed the Agreement.

26. The agreed-upon Unit Price was not even high enough to cover CoreRx's costs to produce each bottle of Product for Bionpharma, let alone to net CoreRx any profit whatsoever. Indeed, CoreRx's costs to manufacture and deliver each bottle of Product to Bionpharma have turned out to be approximately [REDACTED], under general accepted accounting principles (or "GAAP"). This means that, under the Agreement, CoreRx has been forced to take a *loss of [REDACTED] for every bottle delivered to Bionpharma.*

27. On information and belief, the below-market Unit Price has allowed Bionpharma to earn outsized profits on its downstream sales of Product—which, according to public records, it sells for [REDACTED] per bottle. Upon information and belief, Bionpharma has sold approximately 60,000 bottles of Product to date. This translates into approximately [REDACTED] in profits for Bionpharma.

28. On the other hand, CoreRx, for having manufactured and delivered those same 60,000 bottles of Product, at a loss of approximately [REDACTED] per bottle, has suffered losses of nearly [REDACTED].

29. Upon information and belief, the Bionpharma representatives that were on the CoreRx Board at the time the Agreement was being negotiated and entered into improperly and dishonestly influenced the Unit Price to Bionpharma's, taking advantage and exploiting on CoreRx's lack of sophistication with regard to commercial manufacturing to obtain a highly lucrative, low price for Bionpharma for the manufacture and supply of its Product.

30. Upon information and belief, Bionpharma was aware that, had it gone to another CDMO with commercial manufacturing experience to manufacture the Product for it, it would not have obtained such a low price as the Unit Price it persuaded CoreRx to accept for manufacturing and delivering the Product.

31. Furthermore, despite agreeing in the Agreement that the parties would negotiate the Unit Price of the Product on an annual basis (*see* Ex. 1, § 6.2), Bionpharma vehemently resisted any change in the pricing when CoreRx approached it with a proposal to increase the unit price approximately one year following execution of the Agreement, in November 2021, insinuating that such a proposal by CoreRx was in bad faith when it was in fact expressly what the Agreement

called for. A copy of CoreRx's correspondence to Bionpharma, proposing such a price increase, dated November 19, 2021, is attached hereto as **Exhibit 2**.

32. Upon information and belief, Bionpharma's resistance to any increase in the Unit Price was due to the fact that the Unit Price represented a significant victory for Bionpharma, allowing it to pay a price for the manufacture and delivery of the Product that was severely deflated and under-market, allowing Bionpharma to turn around and sell the Product to the public at a significantly higher profit than it would have been able to obtain without exerting undue influence over CoreRx and acting dishonestly and inequitable towards CoreRx in the negotiations process.

B. The Agreement's Multiple Provisions and Representations Regarding the Relevant Intellectual Property and Who Owned It

33. The Unit Price was not the only term in the Agreement about which Bionpharma was dishonest to CoreRx.

34. The Agreement, in order to enable the parties to carry out their intended business purposes, has an entire article, Article 10, titled "Intellectual Property," in which, among other things, specified that through the Agreement Bionpharma was granting CoreRx a license to use *Bionpharma's* "intellectual property" to manufacture the Product for Bionpharma in accordance with the Agreement's terms. (Ex. 1, § 10.3.) Specifically, Section 10.3 of the Agreement provides, in part, as follows:

"Bion[pharma] hereby grants to CoreRx a non-exclusive license to use[] the ***Bion[pharma] Intellectual Property*** solely to Develop the Products in accordance with this Agreement and to Manufacture Products for Bion[pharma] in accordance with this Agreement."

(*Id* (emphasis added).)

35. Through Section 10.3, CoreRx further agreed that it would not "use the ***Bion[pharma] Intellectual Property*** ... for any purpose other than the Manufacture of Products

for Bion[pharma]” under the Agreement (*id.* (emphasis added)), and also agreed that *only* “**Bion[pharma] Intellectual Property**,” and not any other “information, know-how, data or other intellectual property,” was to be used by CoreRx in its manufacture of Product under the Agreement (*id.* at § 10.2 (emphasis added)).

36. Similarly, in a section of the Agreement specifically titled, in bold lettering, “Bion[pharma] Intellectual Property,” CoreRx acknowledged Bionpharma’s ownership of its pre-existing intellectual property and agreed that it would not claim such intellectual property as its own. (*See* Ex. 1, § 10.1) Specifically, Section 10.1 provides as follows:

As between the Parties, Bion[pharma] shall own all right, title and interest in and to the Bion[pharma] Intellectual Property (including any and all information and data contained therein), and CoreRx is not acquiring any ownership interest in any **Bion[pharma] Intellectual Property** (including any and all information and data contained therein) hereunder.”

(*Id.* (emphasis added).)

37. CoreRx also agreed that any improvements or enhancements CoreRx were to make in manufacturing Product for Bionpharma pursuant to the Agreement’s terms, would be automatically deemed to belong exclusively to Bionpharma. (*See id.* at § 10.4(a)), and that in the event of such any such improvement or enhancement would work with Bionpharma to “protect[] Bion[pharma]’s proprietary rights” (*id.* at § 10.4(b)).

38. In turn, the Agreement defines “Bion[pharma] Intellectual Property” in Article 1 to mean “Know-How[] … that is owned or Controlled by Bion[pharma] or its Affiliates during the term of this Agreement and that is necessary for or directly related to the Manufacture, use, sale, offering for sale or importing of the Products.” (*Id.* at § 1.1.) This is specifically defined to include, among other things, “Know-How included in **Bion[pharma] Patent Rights**,” *i.e.*, “those

Patent Rights that cover Bion[pharma] Intellectual Property and are Controlled by Bion[pharma] at any time during the term of this Agreement.” (*Id.* (emphasis added).)

39. Article 10 also contains a section titled “IP Enforcement Matters,” which sets forth the respective obligations of the parties in the event a third-party were to make any claims of infringement or misappropriation against either party based on its use of the “***Bion[pharma] Intellectual Property.***” (*Id.* at § 10.5 (emphasis added).)

40. In addition, amongst various other representations and warranties it made in entering into the agreement, CoreRx represented and warranted to Bionpharma that all Product that CoreRx manufactured under the Agreement would be “Manufactured in accordance with the ***Bion[pharma] Intellectual Property***” unless otherwise agreed by the parties in writing. (*Id.* at § 12.2 (emphasis added); *see also id.* at § 3.2 (CoreRx agreeing again elsewhere to manufacture the Product for Bionpharma “in accordance with Applicable Law … [and] all applicable Bion[pharma] Intellectual Property …”).)

41. In summary, the above provisions specifically and repeatedly required CoreRx, in entering the Agreement, to acknowledge Bionpharma’s ownership of the intellectual property relevant to the manufacture of the Product, as well as any improvements thereto flowing from CoreRx’s efforts under the Agreement, and to promise to manufacture Product in accordance with and respect the proprietary nature of such purported “Bion[pharma] Intellectual Property.”

42. Together, these provisions, among various in the Agreement referring to the “Bion[pharma] Intellectual Property” (*see, e.g., id.* at §§ 3.3, 3.5.1, 3.10, 5.6, 5.8-5.10, 7.1, 7.3) could only be interpreted to mean that Bionpharma held clear ownership, title and interest to the intellectual property that it was licensing to CoreRx and that CoreRx would be required to use in its manufacture of the Product for Bionpharma, in discharge of its contractual duties.

43. In other words, the Agreement's terms, and specifically those provisions discussed above, created a reasonable expectation on the part of CoreRx that Bionpharma had free and clear ownership to the intellectual property to be used by CoreRx in its manufacture and supply of the Product for Bionpharma.

C. The Patent Claims Belonging to Azurity and Ensuing Patent Litigation Against Both Bionpharma and CoreRx

44. Despite the assorted representations and references throughout the Agreement concerning the purported "Bion[pharma] Intellectual Property" and Bionpharma's superior claims thereto, in reality, the manufacture of the Product pursuant to Bionpharma's specifications actually infringes, or at least potentially infringes, patent rights that are validly held by a third-party, Azurity, as set forth below.

45. As also detailed further below, Bionpharma was, moreover, already on notice of Azurity's competing claims at the time it began negotiating the Agreement with Bionpharma in or around the fall of 2020.

46. Azurity is a specialty pharmaceutical drug company focused on developing medication for underserved populations, namely pediatric and geriatric patients. Azurity presently has approximately six (6) FDA-approved products on the market, with approximately ten (10) development projects in its pipeline.

47. One of the products presently manufactured and marketed by Azurity is Epaned®, which is the branded version of the generic Product at issue in the parties' Agreement and in this suit, and has been a brand and product many years in the making. Following nearly a decade of research and development, which cost Azurity many millions of dollars, Epaned® represents a unique solution to the decades-old "pill burden" associated with oral administration of solid

enalapril tablets as well as the patient safety concerns that arise from compounding such oral tablets into solution. In fact, it was the first FDA-approved ready-to-use enalapril solution.

48. Upon information and belief, Epaned® accounts for a significant portion of Azurity’s annual revenues, and was its top-performing product in 2021.

49. Azurity owns a number of patents relating to Epaned® and to oral liquid formulations of enalapril, including U.S. Patent Nos: 9,669,008; 9,808,442; 10,039,745; 10,154,987; 10,772,868; 10,786,482; 10,799,476; 10,918,621; 11,040,023; 11,141,405; and 11,173,141.

50. In or around August 2018, Bionpharma filed Abbreviated New Drug Application (“ANDA”) No. 212408 for a generic enalapril oral solution product similar to Azurity’s Epaned®—which ultimately became the Product at issue here. While Bionpharma’s ANDA for the Product pending approval with the FDA, Azurity’s predecessor, Silvergate Pharmaceuticals, Inc. (“Silvergate”), sued Bionpharma for patent infringement, alleging that the Product infringed several of the patents identified in paragraph 27 above, in December 2018 and in June 2019, and Silvergate brought another such suit against Bionpharma based on another patent in the same family in September 2020. *See Silvergate Pharms., Inc. v. Bionpharma Inc.*, No. 18-1962-LPS (D. Del.); *Silvergate Pharms., Inc. v. Bionpharma Inc.*, No. 19-1067-LPS (D. Del.); *Silvergate Pharms., Inc. v. Bionpharma Inc.*, No. 20-1256-LPS (D. Del.) (the “Silvergate Suits”).

51. Each of the three Silvergate Suits was still pending as of November 2020, when Bionpharma entered into the Agreement with CoreRx.

52. Although the Silvergate Suits have by this time been dismissed or resolved in Bionpharma’s favor, Azurity has a number of other patents related to Epaned® that were not at issue in those suits, including continuation patents that were issued to Azurity only in 2021.

53. Accordingly, Azurity continued to prosecute its patent claims against Bionpharma in relation to the Product in 2021, after Bionpharma had received the ANDA approval from the FDA and accordingly would begin to sell its Product on the market as a lower-priced competitor to Epaned®. Azurity filed one such suit in June 2021, based on Patent No. 11,040,023, in the United States District Court for the District of New Jersey, which was thereafter transferred to the United States District Court for the District of Delaware (the “Delaware District Court”), and another such suit, based on Patent No. 11,141,405, in the Delaware District Court in October 2021.

See Azurity Pharms., Inc. v. Bionpharma Inc., No. 21-1286-LPS (D. Del.); *Azurity Pharms., Inc. v. Bionpharma Inc.*, No. 21-1455-LPS (D. Del.). Both of these suits remain pending.

54. Given that Bionpharma had received ANDA approval for the FDA for the Product, and could therefore begin to sell the Product on the market in or around August of 2021, it began to place orders for the Product with CoreRx pursuant to the terms of the Agreement. Based on, among other things, the non-disclosure of such litigation by Bionpharma and the various representations throughout the Agreement as to “Bion[pharma’s] Intellectual Property,” CoreRx began to fill those orders pursuant to its obligations under the Agreement.

55. As a result, in October 2021, CoreRx was also sued by Azurity for patent infringement in actions commenced in the Delaware District Court and in the United States District Court for the Middle District of Florida. *See Azurity Pharms., Inc. v. CoreRx, Inc.*, No. 21-1522 (D. Del.); *Azurity Pharms., Inc. v. CoreRx, Inc.*, No. 21-2515 (M.D. Fla.) (the “Azurity-CoreRx Suits”). The Azurity-CoreRx Suits also concerned Patent Nos. 11,040,023 and 11,141,405.

56. The Azurity-CoreRx Suits exposed CoreRx to tens or even hundreds of millions of dollars in liability to Azurity, given the damages that are available to a patentee against an infringer

for acts of infringement under the United States Patent Act, 35 U.S.C. §§ 1 *et seq.*, and the manner in which such damages are measured thereunder.

57. Although CoreRx reached a settlement with Azurity with respect to the two Azurity-CoreRx Suits and entered into a corresponding settlement agreement in November 2021 (the “Azurity-CoreRx Settlement,” a true and correct copy of which is attached as **Exhibit 3** hereto), it still has severe exposure flowing from CoreRx’s Agreement with Bionpharma and Bionpharma’s bad faith conduct with respect thereto.

58. Specifically, although Azurity dismissed the Azurity-CoreRx Actions pursuant to the Azurity-CoreRx Settlement, those dismissals were without prejudice to Azurity’s reopening the Actions at a later date. (*See Ex. 3, § 2.1.*)

59. In exchange for these without prejudice dismissals, CoreRx agreed in the Azurity-CoreRx Settlement to cease making, using, selling, importing or offering to sell the Product, but further agreed that, in the event it *were* to re-commence doing any of those things, Azurity could pursue claims for damages against CoreRx stemming from CoreRx’s past as well as its forward-looking instances of infringement. (*See id. at § 2.5; see also id. at §§ 2.2-2.3, 3.*)

60. CoreRx would not have entered into the Agreement with Bionpharma had it been aware that its manufacture and/or supply of the Product according to Bionpharma’s specifications would expose it to infringement or misappropriation claims of a third-party like Azurity, liability for which would likely substantially outweigh the benefits (*i.e.*, profits) that CoreRx expected to gain by entering into the Agreement in the first place.

61. Bionpharma’s bad faith conduct and implicit and explicit representations throughout the Agreement violated the entire spirit of the Agreement, and the mutually beneficial partnership CoreRx believed it was designed to achieve between the parties, by creating a false

impression that it had free and clear ownership of the relevant intellectual property that it was requiring CoreRx use in its manufacture of the Product.

62. Bionpharma's conduct has potentially put CoreRx between the proverbial "rock and a hard place," left to choose between a course of action that would potentially expose it to liability to Azurity (continuing to manufacture the Product), and one that would potentially expose it to liability to Bionpharma for breach of the Agreement (discontinuing its manufacture of the Product).

CAUSES OF ACTION

COUNT I: **Breach of the Contractual Covenant of Good Faith and Fair Dealing**

63. CoreRx realleges and incorporates by reference the allegations in the above paragraphs 1 through 62 as if fully set forth herein.

64. In or around November of 2020, Bionpharma and CoreRx entered into a business partnership intended to increase profits for both parties through combining their respective expertise to manufacture and distribute the Product to market. The parties memorialized their arrangement in the Agreement.

65. The Agreement, which CoreRx and Bionpharma executed on or about November 24, 2020, is a valid and enforceable contract between the parties, supported by adequate consideration and governed by New York law.

66. New York law recognizes that implied in every contract is a covenant of good faith and fair dealing. Accordingly, a covenant of good faith and fair dealing exists with respect to the parties' Agreement.

67. CoreRx has fully performed its obligations under the Agreement and has acted consistent with its inherent duty of good faith and fair dealing. Any deviation by CoreRx from the Agreement was justified by the actions of Bionpharma.

68. Bionpharma's conduct as described throughout these Counterclaims has been in bad faith and in breach of the Agreement's implied covenant of good faith and fair dealing.

69. Specifically, Bionpharma presented an Agreement to CoreRx containing numerous provisions concerning, and references to, Bionpharma's superior title and ownership of what was defined as "Bion[pharma] Intellectual Property," and that explicitly required CoreRx to use said "property" in performance of its own contractual obligations, while knowing that its title to the applicable intellectual property was in fact the subject of ongoing infringement challenges and potentially meritorious infringement claims, of a third-party.

70. At all relevant times both prior to and following execution of the Agreement, Bionpharma had actual knowledge that CoreRx would expose itself to patent infringement liability to Azurity by performing in accordance with the Agreement, thereby knowingly jeopardizing CoreRx's ability to increase its profits—the very purpose of the Agreement—and in fact put CoreRx's entire business at risk of insolvency and, consequently, a need to shutter its operations completely.

71. Bionpharma's conduct as described above has thus deprived CoreRx of the benefit it bargained for in the Agreement and has defeated CoreRx's reasonable expectations and the entire spirit of the Agreement.

72. Bionpharma's aforesaid conduct was knowing, deliberate and willful.

73. CoreRx has sustained damages, and continues to sustain damages, as a result of Bionpharma's aforesaid conduct and breach, in an amount to be determined at trial, including, but

not limited to, fees and costs associated with the defense and settlement of the patent infringement claims that Azurity has brought against CoreRx.

74. Further, Bionpharma's opportunistic and dishonest conduct constitutes an extraordinary showing of dishonest or disingenuous failure to carry out a contract and therefore subjects Bionpharma to punitive damages under New York law.

COUNT II:
Unjust Enrichment

75. CoreRx realleges and incorporates by reference the allegations in the above paragraphs 1 through 74 as if fully set forth herein.

76. During the negotiations of the Agreement, Bionpharma, through its representation on the CoreRx Board, exerted undue influence over CoreRx in order to convince CoreRx to accept a Unit Price that was financially detrimental to CoreRx, and financially lucrative to Bionpharma, without compensating CoreRx for the same.

77. CoreRx agreed to that Unit Price—a Unit Price which not only cut into CoreRx's profits but further caused CoreRx to take monetary losses as a result of entering into the Agreement—on the understanding and belief that the CoreRx Board, including those members who were Bionpharma appointees, would discharge their fiduciary duties to CoreRx and advise CoreRx in a manner that served CoreRx's, and not Bionpharma's, best interests. That did not happen.

78. It is against equity and good conscience to permit Bionpharma to keep the quantifiable benefits—that being, increased profits—derived from this conduct, at CoreRx's expense.

79. CoreRx has been unjustly damaged while Bionpharma has been unjustly enriched through Bionpharma's conduct, and CoreRx is accordingly entitled to a portion of CoreRx's unjustly received profits, in a sum to be determined at trial.

WHEREFORE, Defendant-Counterclaim Plaintiff CoreRx respectfully requests that the Court enter judgment as follows:

- A. Dismissing Plaintiff and Counterclaim-Defendant Bionpharma's Complaint in its entirety and with prejudice;
- B. Denying and each and every demand and prayer for relief contained in the Complaint;
- C. On Defendant and Counterclaim-Plaintiff CoreRx's First Counterclaim, awarding actual and punitive damages to CoreRx in an amount to be determined at trial, together with interest;
- D. On Defendant and Counterclaim-Plaintiff CoreRx's Second Counterclaim, awarding damages to CoreRx in an amount to be determined at trial, together with interest;
- E. Awarding CoreRx its costs and reasonable attorneys' fees; and
- F. Awarding CoreRx such other and further relief as the Court deems just, proper and equitable.

Dated: New York, New York
March 30, 2022

Respectfully submitted,

BUCHANAN INGERSOLL & ROONEY PC

By: /s/ Peter S. Russ
Peter S. Russ
501 Grant St., Suite 200
Pittsburgh, PA 15219-4413
Tel.: (412) 562-8800
Fax: (412) 562-1041
E-mail: peter.russ@bipc.com

-and-

Matthew L. Fedowitz (*pro hac vice*)
1700 K St. N.W., Suite 300
Washington, DC 20006-3807
Tel.: (202) 452-7900
Fax: (202) 452-7989
E-mail: matthew.fedowitz@bipc.com

-and-

Jacqueline M. Weyand
Abigail F. Coster
640 Fifth Ave., 9th Floor
New York, NY 10019-6102
Tel: (212) 440-4400
Fax: (212) 440-4401
E-mail: jacqueline.weyand@bipc.com
abigail.coster@bipc.com

Attorneys for Defendant CoreRx, Inc.

CERTIFICATE OF SERVICE

I hereby certify that on this 30th day of March, 2022, I electronically filed the foregoing Answer to Complaint with Affirmative Defenses and Counterclaims of Defendant CoreRx, Inc. with the Clerk of the Court via the CM/ECF system. Notice of this filing will be served upon all parties by e-mail by operation of the Court's CM/ECF system, and parties may also access the filing through CM/ECF.

Dated: New York, New York
March 30, 2022

/s/ Peter S. Russ
Peter S. Russ